REMARKS

I. Introductory Comments

In the final Office Action under reply, the Examiner has indicated the claims are rejected as follows: under 35 U.S.C. §102(b) as allegedly being anticipated by Andya et al. (U.S. Patent No. 6,267,958) (claims 31-59); and under 35 U.S.C. §112, first paragraph, as allegedly containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

II. Amendments to the Claims

Claims 1-74 were previously pending. Claims 36-41 are amended. Claims 1-30 and 60-74 were withdrawn from further consideration without prejudice by the Examiner. As a consequence, claims 31-59 remain under consideration.

Support for the changes to the claims is identified below. Additional support other than that identified below may exist in the originally filed application for one or more changes to the claims.

Dependent claims 36-41 were each amended to include a comma (",") prior to word "wherein." This change brings into conformity dependent claims 36-41 with all other dependent claims that include a comma (",") prior to the word "wherein."

As support for the changes is found in the application as filed, no new matter is introduced by the entry of the above-identified changes. The changes to the claims are made for clarification purposes only should not be interpreted as acquiescence in any claim rejection.

III. The Restriction Requirement

Applicants reserve their right to petition the Commissioner to review the requirement for restriction, deferring the filing of such petition until after final action on or allowance of the claims, but not later than appeal. See 37 C.F.R. §1.144.

IV. The Rejection Under 35 U.S.C. §102(b)

The Examiner rejected claims 31-59 under 35 U.S.C. §102(b) as allegedly being anticipated by Andya et al. (U.S. Patent No. 6,267,958). Ostensibly, the Examiner has taken the position that each and every element of the rejected claims can be found in Andya et al. notwithstanding the remarks provided with Applicants' June 30, 2006, Reply Under 37 C.F.R. §1.111.

The rejection is respectfully traversed in view of the following remarks.

The standard for anticipation is rigorous requiring that every element of the claimed invention be disclosed by a single prior art reference. *See Minnesota Mining & Mfg. Co. v. Johnson & Johnson Orthopaedics, Inc.*, 976 F.2d 1559, 1565 (Fed.Cir.1992); *Scripps*, 927 F.2d at 1576-77; *Lindemann Maschinenfabrik GMBH, v. American Hoist & Derrick Co.*, 730 F.2d 1452, 1458 (Fed.Cir.1984).

The Examiner begins her substantive remarks in the present Office Action by stating that the "patentability of the product does not depend on its method of production." Citing Andya et al. at claims 1-8 and 47 and column 17, lines 1-40, in particular, the Examiner alleges that the claimed antibody formulation and the referenced antibody formulation both comprise an antibody, diluent, buffer and sucrose as an excipient. The Examiner concludes that the "newly claimed product feature being visually clear upon reconstitution is [an] inherent property of the antibody formulations."

In response, Applicants point out that the claims do not simply recite a reconstituted composition being "visually clear upon reconstitution." Instead, the claims recite (among other things) that the reconstituted composition "is a visually clear reconstituted composition within 10 minutes of being formed." Emphasis added. In view of the different reconstitution times associated with the lyophilized formulations shown in the specification at paragraph **[0162]** (which are also of the type disclosed in Andya et al.) and the spray dried formulations encompassed by the claims, it simply cannot be said that a visually clear reconstituted composition within 10 minutes of being formed is "an inherent property of antibody formulations" generally.

Notwithstanding the claimed product feature (i.e., a composition that "is a visually clear reconstituted composition within 10 minutes of being formed"), the Examiner attempts to bolster her position by pointing out perceived shortcomings of the sample test described at paragraph **[0162]**. Specifically, the Examiner perceives the comparison suffers from the following

shortcomings: (a) the sample test was performed in distilled water and "cannot be extrapolated into the claimed diluent;" (b) the referenced antibody concentration is at 50mg/ml[1] and cannot be extrapolated into the claimed concentration range of about 1000 mg/ml; and (c) the specification discloses that the claimed diluent exceeds reconstituting time of 10 minutes at 190 mg/ml concentration and it is less likely to reconstitute 1000 mg/ml within 10 minutes.

In response to these perceived shortcomings, Applicants point out that concerns such as whether "deionized water" can be "extrapolated to the claimed diluent," whether the antibody concentration can be extrapolated to the claimed concentration range of from about 25 mg/mL to about 1000 mg/mL, and whether the composition is less likely to reconstitute within 10 minutes when the antibody concentration is 1000 mg/mL are immaterial to questions of novelty under 35 U.S.C. §102(b). Rather, what is material is whether the *claimed reconstituted compositions* are novel over the cited art.

Again, Applicants emphasize that their claims require a reconstituted composition having the feature of visual clarity within 10 minutes of being formed. Applicants demonstrated that reconstituted lyophilized compositions -- such as the type disclosed in Andya et al. -- will not inherently become a visually clear reconstituted composition within 10 minutes of being formed. Further, a close reading of Andya et al. only reveals that the "time required for reconstitution will depend, e.g., on the type of diluent, amount of excipient(s) and protein." See Andya et al. at Column 17, lines 23-25. In addition, Andya et al. fails to disclose the feature of a spray-dried powder, a feature recited in the only pending independent claim. Consequently, as the cited art fails to teach each and every feature recited in the claims, the rejection of claims 31-59 under 35 U.S.C. §102(b) should be removed. Reconsideration and removal of the rejection are respectfully requested.

V. The Rejection Under 35 U.S.C. §112, First Paragraph

The Examiner has rejected claims 31-59 under 35 U.S.C. §112, first paragraph, as allegedly failing to comply with the written description requirement. On paragraph 7 of the Office Action, the Examiner alleges

[1] Although it appears the Examiner indicates that "the sample test as in [0162]" had an antibody concentration of 50 mg/mL, paragraph [0162] actually describes a composition having a concentration of 200 mg/mL.

> The specification as file [sic] does not provide a written description for the phrase "visually clear reconstituted composition within 10 minutes of being formed". The specification on p. 23 lines 1-2 discloses the general reconstitution time "within about 10 minutes" and the limitation is not associated with the claimed antibody concentration ranges, especially at about 1000 mg/mL.

The Examiner concludes by pointing to a composition described in the specification that has a reconstitution time that exceeds 10 minutes. Inasmuch as the Examiner alleges that the "limitation is not associated with the claimed antibody ranges," it appears the Examiner has taken the position that the entire scope of the claims (e.g., the claimed antibody concentration ranges) is not enabled.

However, the Examiner has also indicated that the rejection under 35 U.S.C. §112, first paragraph, is a "new matter" rejection. See paragraph 7 of the Office Action.

Because it appears the Examiner has alleged two different bases under 35 U.S.C. §112, first paragraph, to reject the claims, each will be addressed. In the event that Applicants have misunderstood the 35 U.S.C. §112, first paragraph, rejection, the Examiner is asked to clarify the rejection in the next communication.

A. Enablement

The enablement requirement under 35 U.S.C. §112, first paragraph, requires the scope of the claims must bear a reasonable correlation to the scope of enablement provided by the specification to persons of ordinary skill in the art. Union Carbide Chemicals v. Shell Oil. Co. (CAFC 2002) 308 F3d 1167, 64 PQ2d 1545, quoting In re Fisher (CCPA 1970) 427 F2d 833, 166 USPQ 18.

In the present case, the specification provides several working examples in which compositions in accordance with the invention have a reconstitution time of within 10 minutes. Specifically, the reconstitution times of the following compositions are described in the specification: less than four minutes for a composition comprising an antibody in an amount of 100 mg/mL (see formulation 3 in paragraph **[0169]**); within five minutes for compositions comprising an antibody in an amount of 140 mg/mL (see formulations 4 and 5 in paragraph **[0173]**); less than 10 minutes for compositions comprising an antibody in an amount of 190 mg/mL (see formulations 6 and 7 in paragraph **[0179]**); and less than five minutes for a composition comprising an antibody in an amount of 200 mg/mL (see paragraph **[0162]**). In addition, paragraphs **[0060]** to **[0089]**, **[0094]** to **[0100]** and **[0106]** of the specification describe how to make the claimed compositions. Thus, in view of the working examples and entire specification, the entire scope of the claims is enabled.

Applicants acknowledge that their specification describes a composition comprising an antibody in an amount of 190 mg/mL that has a reconstitution time of greater than 10 minutes. See, e.g., "Formulation # 4" in Table IV, on page 41, of the specification. As will be appreciated by the Examiner, however, applicants have the right and obligation to draft claims setting forth the subject matter that applicants regard as their invention.

Applicants respectfully direct the Examiner's attention to paragraph [0106] wherein it is stated that the

> "reconstituted compositions, however, preferably become visually clear within about 15 minutes, more preferably within about 10 minutes, and most preferably within about 5 minutes of adding the diluent." [Emphasis added].

Thus, Applicants teach that certain reconstitution times are *preferred* features of the described compositions and are therefore not necessarily present in *all* compositions. Consistent with their right to claim that which is regarded as their invention, Applicants have drafted claims reciting the *preferred* feature of "a visually clear reconstituted composition within 10 minutes of being formed." As a consequence, it is irrelevant to the present rejection that the Examiner can point to subject matter in the specification (such as "Formulation # 4) that represents a "less preferred" species.

It may be that the Examiner has raised the "greater than 10 minutes reconstitution time" of Formulation # 4 as an example of an "inoperative species" within the scope of the claim. By definition, however, Applicants' currently pending claims do not literally encompass those compositions that do not become "a visually clear reconstituted composition within 10 minutes of being formed." Thus, a composition such as Formulation # 4 does not represent an "inoperative species" within the scope of the claim, but may simply represent a species not literally encompassed by the currently pending claims.

Furthermore, assuming *arguendo* that Formulation # 4 and any other described composition having a "reconstitution time" of greater than 10 minutes does represent an inoperative species within the scope of the claims, it is well settled that the presence of inoperative embodiments within the scope of a claim does not necessarily render a claim nonenabled. The standard is whether a skilled person could determine which embodiments that were conceived, but not yet made, would be inoperative or operative with expenditure of no more effort than is normally required in the art. Atlas Powder Co. v. E.I. duPont de Nemous & Co. 750 F.2d 1569, 1577, 224 USPQ 409, 414 (Fed. Cir. 1984). Here, a skilled person could easily determine whether any given

composition has the feature of being "a visually clear reconstituted composition within 10 minutes of being formed" by following, for example, the procedure set forth in the Experimental and/or paragraph [0151]. Thus, because a skilled person could easily determine which embodiments would be inoperative or operative, the claims satisfy the requirements of 35 U.S.C. §112, first paragraph, even though the Examiner might be able to point to one or more "inoperable embodiments."

B. New Matter

The Examiner indicated in paragraph 7 of the Office Action that the rejection under 35 U.S.C. §112, first paragraph, is a "new matter rejection."

Applicants acknowledge that the feature of "within 10 minutes" was previously introduced into claim 31, while the specification on page 23, lines 1-2, recites "within about 10 minutes."

To the extent that the absence of the term "about" in claim 31 represents the introduction of "new matter," Applicants respectfully submit that such a position is contrary to well-established case law in that a disclosure including multiple ranges provides adequate support for reciting portions of those ranges. *See In re Wertheim*, 191 USPQ 90 (CCPA 1976) (range of 25 to 60% with examples at 36% and 50% found to be adequate description for a range of 35 to 60%); In re Voss, 194 USPQ 267 (CCPA 1977) (range of 20 to 100% provided description for range of 50 to 100%); In re Blaser, 194 USPQ 122 (CCPA 1977) (range of 60 to 200°C provided adequate description for 80 to 200°C); In re Waymouth, 179 USPQ 627 (CCPA 1973) (range of 450 to 700°C was claiming same range as claim specifying a minimum temperature of 580°C); McLaughlin v. Roberts, 197 USPQ 831 (Bd. Pat. App. & Int. 1978) (range of 10 to 79% with preferred ranges of 40 to 79% and 40 to 60% provided adequate support to claim range of 10 to 25%).

Here, Applicants respectfully submit that the disclosure of "within about 10 minutes" on page 23, lines 1-2, of the present specification provides adequate support for reciting "within 10 minutes" based on numerous precedents that show a range (e.g., "within about 10 minutes") provides adequate support for reciting a *portion* of that range (e.g., "within 10 minutes')

Moreover, the specification sets forth reconstitution times (in minutes) of " < 10" (see Table X on page 43), which would be understood by those of ordinary skill in the art to mean

"less than 10" and "within 10," thereby providing an independent basis for introducing the concept of "within 10 minutes."

C. Conclusion

Thus, in view of the foregoing, reconsideration and removal of the rejection under 35 U.S.C. §112, first paragraph, are respectfully requested.

VI. Conclusion

In view of the foregoing, Applicants submit that the pending claims satisfy the requirements of patentability and are therefore in condition for allowance. Reconsideration and withdrawal of all objections and rejections is respectfully requested and a prompt mailing of a Notice of Allowance is earnestly solicited.

If a telephone conference would expedite the prosecution of the subject application, the Examiner is requested to call the undersigned at (650) 620-5506.

Respectfully submitted,
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